**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

| | |
|---|---|
| FWK HOLDINGS, LLC on behalf of itself and all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>SHIRE PLC, SHIRE LLC, SHIRE U.S., INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., AND TEVA PHARMACEUTICALS USA, INC.,<br><br>Defendants. | CIVIL ACTION No.<br><br>CLASS ACTION<br><br>JURY TRIAL DEMANDED |

**CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL**

**TABLE OF CONTENTS**

The plaintiff FWK Holdings, LLC, on behalf of itself and all others similarly situated, for its class action complaint against (1) Shire plc, Shire LLC, and Shire U.S., Inc. (collectively, "Shire") and (2) Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") (Teva collectively with Shire, the "defendants"), alleges, based on personal knowledge as to itself and upon information and belief as to the other allegations, as follows:

## I. INTRODUCTION

1. This case arises from an illegal reverse payment agreement in the market for the attention-deficit/hyperactivity disorder (ADHD) drug Intuniv. Intuniv manufacturer Shire and generic manufacturer Actavis colluded to keep generic Intuniv off the market for over a year and a half in order to prolong Shire's monopoly profits. In April 2013, Shire and Actavis entered into a reverse payment agreement under which Actavis agreed to delay the entry of its ANDA-approved generic Intuniv until December 1, 2014, and in exchange Shire agreed not to produce an authorized generic to compete against Actavis's generic Intuniv during Actavis's 180-day exclusivity period, an agreement worth over $477 million in sales to Shire and approximately $61 million in profits to Actavis as compared to what they would have earned under competitive conditions. Were it not for the deal between Shire and Actavis (a payoff that kept generic Intuniv off the market for over a year and a half and then made Actavis's generic Intuniv the only generic on the market for 180 days), American purchasers of Intuniv would have saved an estimated half billion dollars.

2. This is a civil antitrust action seeking treble damages arising out of the defendants' unlawful impairment of competition for the drug Intuniv. Intuniv's developer, Shire, and the generic manufacturer Actavis, now owned by Teva, collaborated in an unlawful reverse payment agreement to block generic competition in order to share monopoly profits between themselves and, thereby, harm consumers.

3. Intuniv is the Shire brand name for an extended-release tablet form of guanfacine, approved by the FDA on September 2, 2009 – a prescription medication for the treatment of ADHD in children and adolescents. In the 12-month period ending June 30, 2014, Intuniv had U.S. market sales of $335 million. Hundreds of thousands of parents have depended on Intuniv for the treatment of ADHD in their children.

4. The patent and drug regulation laws afforded Shire a period during which no manufacturer could sell a generic version of Intuniv. Until the Hatch-Waxman Act's three-year exclusivity period on Intuniv expired on September 2, 2012, Shire legally occupied 100% of the Intuniv market, charged supra-competitive prices, and earned monopoly profits.

5. When Shire's three-year exclusivity period on Intuniv did expire, generic manufacturers would be able to obtain FDA approval to market equivalent, but much less expensive, generic versions of the drug. A significantly cheaper, medically equivalent, generic version of Intuniv would quickly take over the market. Indeed, in certain states, a pharmacist is required to provide patients with the generic, unless the patient requests the brand drug, or the doctor specifically indicates that the patient must receive the brand drug. Shire's monopoly on Intuniv, along with the supracompetitive profits derived from it, would disappear once generic competitors entered the market in September 2012.

6. Facing the imminent and certain erosion of brand sales due to generic entry and substitution, Shire engaged in a scheme to block generic competition by effectively paying generic drug manufacturer Actavis to delay its market entry until December 1, 2014, and thereby block other generic entrants until June 2015. Absent Shire's agreement with Actavis, and Actavis's expectation and knowledge that such a deal was in the offing, Actavis would likely have entered the market no later than in May 2013.

7. On December 29, 2009, Actavis filed the first Abbreviated New Drug Application (ANDA) seeking FDA approval for generic Intuniv. Actavis argued that all three of Shire's patents on Intuniv were either invalid or not infringed. As the first generic filer, Actavis was potentially entitled to 180 days during which other generic manufacturers would not be allowed to sell generic Intuniv (aside from an Intuniv "authorized generic" sold by Shire).

8. Following Actavis's ANDA, other generic manufacturers also filed ANDAs for Intuniv: Teva on January 25, 2010; TWi Pharmaceuticals on January 28, 2010; Mylan on November 30, 2010; and Sandoz on December 28, 2010.

9. Shire filed patent infringement suits against Actavis, Teva, TWi, and Anchen (which was spun off from TWi) in the District of Delaware. The filing of the lawsuits triggered a 30-month stay under applicable law so that the ANDAs could not be approved for 30 months (from the date the generic manufacturer gives notice to Shire) while the lawsuits were pending, unless they were resolved in favor of the generic manufacturer. Unless the generic manufacturers prevailed in the patent cases, the FDA could not approve Actavis's ANDA until October 2, 2012, and could not approve any other ANDA until Actavis's 180-day exclusivity lapsed or expired.

10. On September 4, 2012, Shire settled its patent cases with TWi and Anchen. The settlement provided: (a) Anchen could launch a generic Intuniv on July 1, 2016; (b) if Shire launched an authorized generic, Anchen would be the distributor of Shire's authorized generic; and (c) in the event of an unlicensed Actavis launch of generic Intuniv, Anchen would be the distributor of Shire's authorized generic.

11. From September 17 through 20, 2012, a bench trial was held on Shire's claims against Actavis and Teva for infringement of two of Shire's Intuniv patents. The court did not render a decision at that time.

12. On October 2, 2012, Actavis's 30-month stay expired, and on October 5, 2012, Actavis received final approval of its ANDA. Now that Actavis had received timely approval, when Actavis launched a generic Intuniv, it would be guaranteed 180 days during which no other generic manufacturer could launch a generic Intuniv, except for an authorized generic.

13. On April 25, 2013, Shire and Actavis settled their lawsuit through a reverse payoff to Actavis. Although Actavis had final FDA approval to launch its generic Intuniv, Actavis agreed in the settlement that it would delay launch of its ANDA-approved generic Intuniv for over a year and a half, until December 1, 2014. In exchange for this delay, Shire agreed that, upon Actavis's eventual launch of a generic, Shire would not release an authorized generic during Actavis's 180-day exclusivity period. Shire and Actavis knew that Actavis's profits during the 180-day exclusivity period would be vastly increased by Shire's not competing with an authorized generic, so much so that Actavis agreed to kickback to Shire a portion of these profits through a 25% payment, styled as a "royalty," on gross profits. The arrangement resulted (i) in Shire maintaining its Intuniv monopoly, without generic competition, through December 1, 2014, and (ii) in Actavis enjoying a 180-day exclusivity period during which it would not face competition from any other generic, including Shire's authorized generic.

14. In the absence of this settlement agreement, Shire would have launched an authorized generic during that 180-day period (likely with Anchen as its distributor, as promised to it). Instead, Shire obtained a longer period of Intuniv brand exclusivity from May 2013 through December 2014, without Actavis's generic as competition, in exchange for Shire

not launching an authorized generic to compete with Actavis's generic during Actavis's 180-day period of generic exclusivity.

15. Shire's agreement with Actavis was a collusive agreement to maintain a monopoly market. Shire's promise not to launch an authorized generic during Actavis's exclusivity period was worth tens of millions of dollars to Actavis: it was a large reverse payment. As a result of Shire's and Actavis's actions, which are unlawful and actionable under the federal antitrust laws, generic competition for Intuniv was delayed from at least May 2013 through December 1, 2014, requiring purchasers to pay substantially higher prices.

16. This suit, brought under federal antitrust laws, seeks to recover the overcharges made by direct purchasers of Intuniv as a result of the defendants' unlawful and anticompetitive practices.

## II. PARTIES

17. The plaintiff FWK Holdings, LLC ("FWK" or the "Plaintiff") is a limited liability company organized under the laws of the State of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Co., which, during the class period, as defined below, purchased Intuniv and/or generic Intuniv directly from the Defendants and suffered antitrust injury as a result of the anticompetitive conduct alleged herein.

18. The defendant Shire U.S., Inc. maintains its principal place of business and "US Operational Headquarters" at 300 Shire Way, Lexington, Massachusetts 02421. Shire's Lexington, Massachusetts facility is its largest facility and contains offices, labs, manufacturing, and warehousing capabilities. Shire maintains another facility in Cambridge, Massachusetts that contains manufacturing and warehousing facilities and offices. Throughout the Class

Period, Shire U.S., Inc. marketed and sold Intuniv in Massachusetts and elsewhere. Upon information and belief, Shire U.S., Inc. is the manufacturer and distributor of Intuniv.

19. The defendant Shire LLC is a Kentucky limited liability company with its principal place of business at 9200 Brookfield Court, Florence, Kentucky 41042. Shire LLC is a successor entity to Shire Laboratories, Inc., a party to the anticompetitive reverse payment agreements at issue herein. Shire LLC develops, manufactures, and sells brand and generic pharmaceutical products in the United States, including Intuniv. Throughout the Class Period, Shire LLC marketed and sold Intuniv in Massachusetts and elsewhere.

20. The defendant Shire plc is a public limited company incorporated in Jersey in the Channel Islands, with its principal place of business at 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. Shire plc is the parent company of Shire U.S., Inc. and Shire LLC.

21. The defendant Teva Pharmaceutical Industries Ltd. (Teva Ltd.) is a company incorporated in Israel with its principal place of business at 5 Basel St., Petak Tikvah, Israel 49131.

22. The defendant Teva Pharmaceuticals USA, Inc., based in North Wales, PA, is a Delaware corporation and the American subsidiary of Teva Ltd. Teva USA manufactures and sells generic pharmaceuticals in the United States.

23. Actavis Elizabeth LLC is a Delaware limited liability company. Actavis Elizabeth LLC developed, manufactured, marketed, and sold generic pharmaceutical products in the United States, including generic Intuniv. On information and belief, Actavis Elizabeth LLC was a party to the anticompetitive reverse payment agreement at issue herein. During the Class Period, Actavis Elizabeth LLC conducted business in Massachusetts and elsewhere. On information and belief, Actavis Elizabeth LLC is a subsidiary of Teva.

24. Actavis LLC is a Delaware limited liability company. Actavis LLC developed, manufactured, marketed, and sold generic pharmaceutical products in the United States, including generic Intuniv. On information and belief, Actavis LLC was a party to the anticompetitive reverse payment agreement at issue herein. During the Class Period, Actavis LLC conducted business in Massachusetts and elsewhere. On information and belief, Actavis LLC is a subsidiary of Teva.

25. Actavis Inc. was a Nevada corporation. Upon information and belief, Actavis Inc. owned and controlled Actavis Elizabeth LLC and Actavis LLC during the Class Period. Actavis Inc. developed, manufactured, marketed, and sold generic pharmaceutical products in the United States. During the Class Period, Actavis Inc. conducted business in Massachusetts and elsewhere.

26. On August 2, 2016, Teva Ltd. acquired Actavis from Allergan plc, making Teva Ltd. the successor and/or parent company of Actavis, Inc., Actavis Elizabeth LLC, and Actavis LLC, and either the successor to, or beneficiary from, the reverse payment agreement between Shire and Actavis. By acquiring Actavis, Teva became successor to the Plaintiff's claims against Actavis.

27. All of the defendants' wrongful actions described in this complaint are part of, and in furtherance of, the illegal monopolization and restraint of trade alleged herein, and were authorized, ordered, and/or undertaken by the defendants' various officers, agents, employees, or other representatives while actively engaged in the management of the defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, and/or with the actual, apparent, and/or ostensible authority of the defendants.

## III. JURISDICTION AND VENUE

28. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 & 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by the plaintiff and members of the class resulting from the following: (i) the defendants' unlawful monopolization of Intuniv; and (ii) the defendants' conspiracy to restrain trade in the United States market for Intuniv and its generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1332(d) (class action), 28 U.S.C. § 1337(a) (antitrust), and 15 U.S.C. § 15 (Clayton Act).

29. Venue is appropriate within this district under 15 U.S.C. § 15(a) (Clayton Act), 15 U.S.C. § 22 (nationwide venue for antitrust matters), and 28 U.S.C. §1391(b) (general venue provision). The defendants transact business within this district, and the defendants transact their affairs and carry out interstate trade and commerce, in substantial part, in this district. Further, the Defendants and/or their agents may be found in this district.

30. The defendants' conduct was within the flow of, and was intended to and did have a substantial effect on, interstate commerce of the United States, including in this district.

31. During the Class Period, Shire manufactured, sold, and shipped Intuniv in an uninterrupted flow of interstate commerce.

32. During the Class Period, each defendant, or one or more of each defendant's affiliates, used the instrumentalities of interstate commerce to join or effectuate the conspiracy. The scheme in which the defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

33. The Court has personal jurisdiction over each defendant. Each defendant has transacted business, maintained substantial contacts, and/or committed overt acts in

furtherance of the illegal scheme and conspiracy throughout the United States, including in this district. The scheme and conspiracy have been directed at, and have had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

## IV. REGULATORY FRAMEWORK

### A. The Regulatory Structure for Approval of Brand and Generic Drugs

#### 1. Approval of New Drugs and Their Associated Patents

34. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA"), governs the manufacture, sale, and marketing of prescription pharmaceuticals in the United States. Under the FDCA, the manufacturer of a new drug must obtain FDA approval to sell the drug by submitting a New Drug Application (NDA). 21 U.S.C. § 355. An NDA must contain scientific data demonstrating that a drug is safe and effective. New drug applicants, however, are not required, and usually do not try, to show that their new drug product is superior to another similar, already approved, product.

35. The NDA must also identify any patents claimed to cover the new drug. 21 U.S.C. § 355(a), (b).

36. After FDA approval of an NDA, the brand drug's manufacturer may list any patents in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book"), that the brand manufacturer reasonably believes could be asserted against a generic manufacturer that manufactures, uses, or sells a generic version of the brand drug. 21 U.S.C. §§ 355(b)(1) & (c)(2).

37. The FDA relies solely on the brand manufacturer to provide an honest appraisal of its patent's (or patents') validity and applicability, as the FDA does not have the resources,

expertise, or authority to analyze the manufacturer's patent(s). By listing patents in the Orange Book, the FDA is merely performing a ministerial act.

**2. Approval of Generic Drugs Under the Hatch-Waxman Amendments**

38. In 1984, Congress amended the FDCA with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the Hatch-Waxman Amendments.

39. The Hatch-Waxman Amendments simplified the regulatory process for generic manufacturers. Previously, generic applicants had to follow the same steps as an applicant filing an NDA, including conducting costly and time-consuming clinical trials to establish safety and efficacy. This process delayed the approval of generic drugs, or deterred companies entirely from manufacturing generic drugs, and deprived drug purchasers of the benefit of generic competition.

40. Under the Hatch-Waxman Amendments, a manufacturer seeking approval to sell a generic version of a brand drug could file an ANDA. An ANDA relies on the scientific findings of safety and efficacy included in the brand manufacturer's NDA. The ANDA filer need only show bioequivalence to the brand drug, and is not required to make an independent showing of safety or efficacy. Bioequivalence means that the generic product delivers substantially the same amount of active ingredient into a patient's blood stream for the same amount of time as does the corresponding brand drug and, therefore, has the same clinical effect.

41. The FDA assigns generic drugs that are therapeutically equivalent to their brand counterpart an "AB" rating. AB-rated drugs must be (a) bioequivalent to the brand drug, and (b) the same formulation as the brand drug. For example, a tablet formulation cannot be AB-rated to a capsule formulation, even if it is bioequivalent to the capsule.

42. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products that contain identical amounts of the same active ingredients, have the same route of administration and dosage form, and meet applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and, therefore, may be substituted for one another. 21 U.S.C. § 355(j)(8)(B).

**3. Paragraph IV Certification for a Generic Drug**

43. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any valid patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. No patent for the brand drug has been filed with the FDA (a "paragraph I certification");

ii. The patent for the brand drug has expired (a "paragraph II certification");

iii. The patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date (a "paragraph III certification"); or

iv. The patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

*See* 21 U.S.C. § 355(j)(2)(A)(vii).

44. A paragraph IV certification constitutes a constructive act of infringement, granting a brand drug manufacturer standing to sue the ANDA applicant. The brand manufacturer's right to sue is joined with the power to delay generic approval. If the brand manufacturer initiates a patent infringement action against the generic ANDA filer within 45 days of receiving notification of the paragraph IV certification, the FDA will not grant final approval of the ANDA until the earlier of (a) 30 months from the date of the notification, or (b)

the issuance of a decision by a court that the patent for the brand drug is invalid or not infringed by the generic manufacturer's ANDA product. 21 U.S.C. § 355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant only "tentative approval" of the ANDA, even if the FDA determines that the ANDA would otherwise be ready for final approval. Thus, unless the generic manufacturer obtains a court order declaring the brand manufacturer's patent invalid or not infringed, the FDA cannot authorize the generic manufacturer to market its product until the 30-month period elapses.

45. As an incentive to generic drug manufacturers to seek early approval of generic alternatives to brand drugs, the first generic drug manufacturer to file an ANDA containing a paragraph IV certification typically receives a period of protection from competition from other generic versions of the drug approved through the ANDA process.

**B. Characteristics of the Pharmaceutical Marketplace**

46. The marketplace for the sale of prescription pharmaceutical products in the United States contains a unique and significant feature that can be exploited by a brand manufacturer to extend its monopoly over a particular product. In most industries and marketplaces, the person who selects a product for purchase also pays for that product. Therefore, in most industries and marketplaces, the price of the product plays a predominant role in the person's choice of products and, consequently, manufacturers have a strong incentive to lower the price of their product to maintain profitability.

47. In the pharmaceutical marketplace, by contrast, there is a disconnect between product selection and payment. State laws require pharmacists to dispense only the drug that is prescribed to a patient by the patient's physician. Thus, the patient's physician chooses the product the patient will receive, with the patient (and in many cases the patient's insurer) only permitted to purchase and pay for the specific drug prescribed by the physician. A patient's (or

insurer's) inability to obtain a drug without a prescription disconnects the product selection from the payment obligation.

48. Pharmaceutical manufacturers can exploit this disconnect. Brand manufacturers employ armies of sales representatives, known as "detailers," who descend upon physicians' offices to persuade physicians to prescribe their manufacturer's products. The detailers typically do not discuss the cost of the brand products with the physicians.

49. Physicians typically are not aware of the relative costs of brand pharmaceutical products; but even when physicians are aware of the relative cost, physicians are understandably insensitive to price differences because they do not pay for the products themselves. As a result, in the pharmaceutical marketplace, price plays an abnormally unimportant role in product selection.

50. Where two manufacturers each sell a drug that serves a similar therapeutic function, and each manufacturer uses a significant detailer force, the two similar drugs are often sold at very similar, high prices, eliminating any consumer benefit from that "competition." This circumstance, which includes two separate (and expensive) detailer forces, stands in stark contrast to the circumstance in which the competitor is selling a bioequivalent generic without a detailer force. There, the generic price is significantly lower than the brand price, and purchasers benefit, as Congress intended by the Hatch-Waxman Amendments.

51. When the relative importance of the price difference between two brand pharmaceuticals (with no generic version available) is low, the price elasticity of demand – the extent to which sales go down when price goes up – is, by definition, also low. In turn, brand manufacturers have the ability to raise or maintain prices substantially above competitive levels, without losing sales. The ability to raise prices above competitive levels without losing sales is referred to by economists and antitrust courts as market power or monopoly power.

Thus, the overall effect of the nature of the pharmaceutical industry and its marketing practices, described above, is often to allow brand manufacturers to gain and maintain monopoly pricing power, restrained only by competition from AB-rated generics.

52. Congress sought to address the prescription pharmaceutical market's disconnect from market forces, which results in anticompetitive prices for consumers, and to restore some of the normal competitive pressures to the pharmaceutical marketplace, by providing incentives for the rapid development and sale of generics under the Hatch-Waxman Amendments.

53. States have addressed the disconnect by adopting drug product substitution laws that permit (or sometimes require) pharmacists to dispense AB-rated generic versions when the more expensive equivalent brand drug is prescribed, unless the physician specifically indicates "dispense as written," "brand medically necessary," or other similar language, or the patient specifically requests the brand drug. These laws reduce the impact of the pharmaceutical market's disconnect between product selection and payment by creating requirements or incentives to substitute the lower-priced generic for the brand drug at the pharmacy counter.

54. The Congressionally created incentives for generics, coupled with state substitution laws, prevent brand pharmaceutical manufacturers from exploiting the pharmaceutical marketplace disconnect between product selection and payment: the monopoly power of brand pharmaceutical manufacturers is significantly reduced, and certain competitive pressures are restored to the pharmaceutical marketplace.

## C. The Effect of Generic Drugs on Competition

55. As between bioequivalent generic drugs and their brand-name counterparts, the only basis for competition between generics, or between generics and the brand drug, is price.

56. Due to the price differences between brand and generic drugs, and other institutional features of the pharmaceutical industry (*i.e.*, automatic substitution of the generic

for the brand drug at certain pharmacies), the launch of a generic product results in the generic drug quickly taking over a large part of the brand drug's market. Pharmacists liberally and substantially substitute the generic drug when presented with a prescription for the brand drug. Moreover, since passage of the Hatch-Waxman Act, every state has adopted substitution laws requiring or permitting pharmacies to substitute generic drug equivalents for brand drug prescriptions.

57. Thus, once a generic hits the market, it quickly erodes the sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months after launch, and 90% of the brand's unit drug sales after a single year. This competition results in dramatic savings for drug purchasers.

58. Until a generic version of the brand drug enters the market, there is no bioequivalent generic drug to compete with and substitute for the brand drug. Therefore, without generic competition, the brand manufacturer can continue to profitably charge supra-competitive prices. However, the introduction of a generic drug results in a predictable and rapid loss of revenue for the brand drug seller. Moreover, once multiple generics have entered the market, total revenue for the manufacturer of the brand drug declines to a small fraction of the amount received prior to generic entry.

59. As a result, brand manufacturers, such as Defendants, view competition from generic drugs as a grave threat to their revenues and profit margins.

**D. The Effect of Generic Drugs on Price**

60. Typically, when there is a single generic competitor, such as an authorized generic, generics are 10-25% less expensive than their brand counterparts. This discount typically increases to between 50% and 80% (or more) when there are multiple generic competitors available. The FTC estimates that at the point one year after a generic enters the

market, generic drugs sell on average at an 85% discount to the brand price. The Hatch-Waxman Act and state substitution laws drive this competition.

**1. The First Generic ANDA Filer Receives a Period of Statutory, or de facto, Exclusivity**

61. Generics may be classified as (i) first filer generics, (ii) later generic filers, and (iii) authorized generics.

62. To encourage manufacturers to seek approval of generic versions of brand drugs and challenge the validity and/or enforceability of patents or invent around patents, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer a 180-day period to market the generic version of the drug, free from competition from other ANDA filers. During this time, the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. That is, when a first filer generic files a substantially complete ANDA and certifies that the brand manufacturer's unexpired patents, listed in the Orange Book as covering the brand product, are either invalid or not infringed by the generic, the FDA cannot approve a later generic company's ANDA until that first filer generic has been on the market for 180 days (or until the first filer generic's exclusivity has been forfeited or relinquished). 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). This means the first approved generic drug is the only available ANDA-based generic drug for at least six months, with the brand manufacturer permitted, but not required, to produce its own "authorized generic" during that 180-day time period. This permits the generic first filer to (a) monopolize the generic market or compete only with the brand manufacturer's authorized generic, and (b) charge a significantly higher generic price than would prevail if there were additional generics available to generate price competition.

63. As the Supreme Court recognized in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013), "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first-filer generic.

64. First-filer generics that wait until all Orange Book-listed patents expire before marketing their product do not get the 180-day period of exclusivity to market their product without competition from other ANDA generics.

65. This 180-day window is referred to as the first-filer's six-month or 180-day exclusivity. The label, however, is a bit of a misnomer; while later ANDA filers must wait six months after the first filer generic's market entry to get final FDA approval, a brand manufacturer may market its own NDA-approved product as an "authorized" generic at any time.

**2. The First AB-Rated Generic is Priced Below the Brand Drug**

66. The value of first filer generic's 180-day exclusivity period is greatly diminished if the brand manufacturer launches an authorized generic.

67. Experience and economic research show that the first generic manufacturer to launch tends to price its product only slightly below the price of its branded counterpart. Because state substitution laws either require or permit the substitution of an AB-rated generic for a brand prescription, the first generic manufacturer often quickly captures a large market share, even with only a slight discount in price to the brand drug.

68. Thus, a significant portion of a first-filer generic's profit is regularly earned during the generic's exclusivity period.

69. When no other generic is on the market, the first filer prices its product in relation only to the brand product, which keeps the generic price much higher than when the first-filer generic faces competition from other generics. Because the brand company rarely

drops the brand drug price to match the first-filer generic's price, the first-filer generic does not face the price competition present when additional generic products are available. Consequently, a first filer generic earns substantially greater sales and profits when there is no authorized generic (or later generic filers) on the market.

**3. Later Generics Drive Prices Down Farther**

70. When multiple generic competitors enter the market, price competition between the generic competitors drives prices down significantly. Multiple generic sellers typically compete vigorously over price, driving prices down toward marginal manufacturing costs.

71. According to the FDA and the FTC, the point of the greatest price reduction for pharmaceutical products is when the number of generic competitors goes from one to two. In that situation, there are two identical commodities that compete on price. Some typical estimates are that a single generic launch results in a near-term retail price reduction of 10%, but once there are two generics, near-term retail price reduction may reach 50%.

**4. Authorized Generics, Like All Generics, Drive Prices Down**

72. A brand manufacturer may sell a generic version of its brand drug, an "authorized generic," at any time. An authorized generic is chemically identical to the brand drug and is manufactured under the brand drug's NDA, but is sold as a generic product in a different package through either the brand manufacturer's generic subsidiary (if it has one) or through a third-party distributor.

73. Brand drug manufacturers facing competition from generics have large incentives to produce their own authorized generic in order to obtain some of the generic market. A study analyzing three examples of authorized generics found, "[f]or all three products, authorized generics competed aggressively against independent generics on price,

and both the authorized and independent generics captured substantial market share from the brand."[1]

74. For the brand manufacturer, launching an authorized generic during the generic first filer's 180-day exclusivity period provides a low-cost, low-risk means of retaining some of the market share, sales and revenue that its brand drug would otherwise lose to the generic first filer.

75. But first-filer generic manufacturers also have substantial incentives to avoid competition from an authorized generic. Studies have found that authorized generics both significantly lower the price of the generic drugs on the market and capture a significant amount of the first filer generic's market share.

76. Thus, competition from an authorized generic substantially reduces drug prices and the revenue of the first-filer generic; indeed, if the first-filer generic has regulatory or de facto exclusivity, an authorized generic can reduce the revenue of the first filer generic by more than half. Conversely, the absence of an authorized generic can more than double the first filer generic's revenue.

77. Freedom from an authorized generic during the initial 180-day exclusivity period is, thus, exceedingly valuable to the generic first filer.

78. Thus, in exchange for the brand manufacturer's agreement not to produce an authorized generic, a generic manufacturer can benefit greatly by agreeing to delay its entry into the market (extending the brand drug's monopoly time period). With an agreement from a brand manufacturer to forebear launching an authorized generic, known as a "no-AG agreement," a generic manufacturer can be assured of selling into a closed market for generics

[1] E.R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 Health Affairs 790, 796 (2007).

during its exclusivity period, free of generic competition and the resulting price and revenue reductions.

## E. Brand Manufacturers Can Employ Multiple Tactics to Block Generic Competition

79. Competition from lower-priced AB-rated generic drugs saves drug purchasers billions of dollars a year. These savings, however, result in lower profits for brand drug companies. Brand manufacturers thus seek to extend their monopolies for as long as possible.

### 1. Reverse Payments

80. In connection with the resolution of patent litigation arising out of paragraph IV certifications, brand manufacturers pay off generic competitors in exchange for delaying their entry into the market. These agreements not to compete are known as "reverse payment agreements." Brand and generic manufacturers execute reverse payment agreements as purported settlements of patent infringement lawsuits that brand manufacturers file against generic manufacturers.

81. In a typical reverse payment agreement, the brand manufacturer pays a generic manufacturer to (a) delay or abandon market entry, and (b) abandon the invalidity and unenforceability challenges to the brand manufacturer's patents. The brand manufacturer preserves its monopoly by paying some of its monopoly profits to the generic manufacturer, and the generic manufacturer agrees to delay marketing its product, allowing the brand manufacturer to have an extended monopoly period.

82. In the 1990s, these agreements took the form of cash payments from the brand manufacturer to the generic competitor. As a result of regulatory scrutiny, congressional investigations, and class-action lawsuits, brand manufacturers and generic competitors have entered into increasingly elaborate agreements in an attempt to hide the fundamentally anticompetitive character of these agreements and avoid liability.

83. In an increasing number of instances, brand manufacturers disguise the reverse payment to a first-filing generic manufacturer by including in the patent litigation settlement agreement a no-AG promise.

84. When a brand manufacturer agrees to a no-AG clause in exchange for delaying generic entry, the additional profits gained by causing delay to generic competition to achieve a longer monopoly period significantly outweigh any profit that could have been gained from selling an authorized generic. The bottom line is that the brand manufacturer gains a longer period of monopoly profits by delaying the onset of generic competition, and the generic first filer maintains higher generic sales and pricing during its 180-day exclusivity period. Thus, no-authorized generic agreements allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

85. Payment to the first filer in the form of no-AG promise is like a cash payment by the brand manufacturer to the first filer generic not to compete. But, this version of pay-for-delay through a no-AG agreement is even worse for purchasers than a naked cash payment. Without an AG and generic competition, the generic price remains high, and purchasers are overcharged twice: (1) during the period when the generic delays entry, allowing the brand manufacturer to continue its monopoly; and (2) when the generic enters the market but the price remains high because there is no competition from an AG.

86. Due to this double overcharge, courts have nearly universally found that no-AG promises violate the antitrust laws. As the First Circuit explained in considering a no-AG agreement, "antitrust scrutiny attaches not only to pure cash reverse payments, but to other forms of reverse payment that induce the generic to abandon a patent challenge, which unreasonably eliminates competition at the expense of consumers." *In re Loestrin 24 Fe Antitrust*

*Litig.*, 814 F.3d 538, 550 (1st Cir. 2016); *see also In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 392 (D. Mass. 2013) ("This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone.") (citing *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013)).

**2. Bottlenecking the Generic Market**

87. In many circumstances, a first-filer generic can help the brand manufacturer game the system by delaying not only its own market entry, but also the market entry of all other generic manufacturers. When the first filer agrees to delay marketing its generic drug, it also delays the start of the 180-day period of generic market exclusivity, sometimes referred to as "exclusivity parking." This tactic creates a bottleneck because later generic applicants cannot launch their generics until the first generic applicant's 180-day exclusivity has elapsed or is forfeited.

## V. FACTS

88. On September 2, 2009, the FDA approved Shire's drug Intuniv for the treatment of ADHD in children and adolescents.

89. Shire caused to be listed in the FDA Orange Book U.S. Patent Nos. 5,854,290 (the '290 patent), 6,287,599 (the '599 patent), and 6,811,794 (the '794 patent) as covering Intuniv 1-, 2-, 3-, and 4-mg tablets.

90. The active ingredient of Intuniv, guanfacine hydrochloride, was first marketed in 1986 and had been off patent and in the public domain for years at the time of Intuniv's 2009 approval. The '290 patent is a method-of-use patent, and the '599 and '794 patents cover the coating that enables the gradual release of the active ingredient, guanfacine hydrochloride. Formulation or method-of-use-patents can be easier to overturn than patents concerning the composition of matter of an active ingredient. Shire's strategy of focusing on new

reformulations of off-patent active ingredients kept its development costs down, but made its patent portfolio weak.

91. Shire knew that the '290, '599, and '794 patents were weak and would likely be invalidated if challenged, but listed the patents in the Orange Book to deter potential generic entrants. The '290 patent was so weak that Shire would later dedicate (surrender) it during patent litigation. Indeed, the '290 patent was subsequently found by a court to be invalid.

92. The Hatch-Waxman Act gave Shire a three-year Intuniv exclusivity period, which expired on September 2, 2012. Until that date, Shire legally occupied 100% of the Intuniv market, charged supracompetitive prices, and earned monopoly profits.

93. Shire knew that when its three-year exclusivity period on Intuniv did expire, (a) generic manufacturers would obtain FDA approval to market equivalent, but much less expensive, generic versions of the drug, (b) the vast majority of the market would go to those cheaper generics, and (c) Shire's monopoly on Intuniv, along with its supracompetitive profits, would disappear.

94. Facing the imminent and certain erosion of brand sales due to generic entry and substitution, Shire engaged in a scheme to block generic competition, employing a series of unlawful tactics.

95. On December 29, 2009, generic drug manufacturer maker Actavis filed the first ANDA seeking FDA approval for generic Intuniv. Actavis's ANDA included a paragraph IV certification stating that all three of Shire's patents on Intuniv were either invalid or not infringed. As the first generic filer, Actavis was potentially entitled to 180 days of restricted competition from other generics (other than "authorized generics" sold by Shire itself).

96. Following Actavis's ANDA, other generic manufacturers also filed ANDAs for Intuniv. Teva filed on January 25, 2010, TWi filed on January 28, 2010, Mylan filed on November 30, 2010, and Sandoz filed on December 28, 2010.

97. Paragraph IV notice letters were sent to Shire by Teva on March 12, 2010, Actavis on April 2, 2010, and Anchen on April 23, 2010.

98. Shire filed patent infringement suits in the District of Delaware against Teva on April 22, 2010, against Actavis on May 12, 2010, and against Anchen (which was spun off from TWi) on June 2, 2010. The lawsuits triggered a 30-month stay, mandating that the ANDAs could not be approved for 30 months from the date of the notifications while the lawsuits were pending, unless the cases were resolved in favor of the generic manufacturer. As long as the generic manufacturers did not prevail in the patent litigations, the FDA could not approve Actavis's ANDA until October 2, 2010, and could not approve any other ANDA until Actavis's 180-day exclusivity period ended.

99. On August 2, 2010, Shire's lawsuits against Actavis, Teva, and Anchen were consolidated.

100. In March 2012, just days before Shire would have to provide expert reports on the '290 patent in the consolidated litigation, Shire dedicated the '290 patent to the public, effectively surrendering it.

101. Shire was expected to lose. Investment bank research analysts that followed the litigation held the belief that Shire would lose and expected that generics would enter the market as soon as the litigation concluded. In fact, BNP Paribas wrote in June 2012, "[w]e now adopt a bear scenario with Shire losing the litigation vs generic makers (17 Sept 2012) on the two remaining formulation patents ('599/'794) and the entry of generics in mid-2013 after a 6-9 month trial."

102. On September 4, 2012, just two days after Shire's brand exclusivity period expired, Shire settled with TWi and Anchen. The settlement allowed Anchen to launch its generic Intuniv on July 1, 2016; allowed Anchen to distribute Shire's authorized generic; and, in the event of an unlicensed Actavis launch of generic Intuniv, allowed Anchen to enter the market immediately as Shire's authorized generic.

103. From September 17 through 20, 2012, a bench trial was held on Shire's claims against Actavis and Teva for infringement of the remaining two patents, the '599 and '794 patents. The court did not render a decision at that time.

104. On October 2, 2012, the 30-month stay on Actavis's ANDA expired. On October 5, 2012, Actavis received final FDA approval of its ANDA. Because Actavis was the first filer for the product and had timely acquired approval, Actavis was guaranteed 180 days during which no other ANDA-approved generic manufacturer could launch its own generic Intuniv.

105. In early 2013, Actavis CEO Paul Bisaro stated that time was "of the essence" for a settlement with Shire, believing that a decision in the litigation in Actavis's favor was imminent, and if Actavis could settle before the decision came down, Shire would agree to terms highly advantageous to Actavis.

106. On April 25, 2013, Shire and Actavis settled their lawsuit. The settlement required that Actavis delay its launch of generic Intuniv until December 1, 2014, paying Shire a 25% royalty on gross profits during the 180-day exclusivity period. This agreement contained an implicit or explicit no-AG clause because it was structured to allocate the market during the 180 days of exclusivity between Shire and Actavis. Typically, during that period, Shire (with an AG) and Actavis (with its generic) would compete for generic sales based on price, driving down the price that drug purchasers paid for generic versions. But, instead of this

procompetitive situation, Shire and Actavis agreed on an anticompetitive situation whereby Shire would not launch an AG but, instead, would share (through "royalty" payments) in the prices that Actavis was able to charge for its generic. Actavis would not have agreed to pay a royalty if Shire had not promised to forego launching an AG because that would have meant paying the very company that was cannibalizing Actavis's generic profits. Because of Shire's agreement to not enter the generic market during the 180 days of exclusivity, Actavis had no generic competition and was able to maintain much higher prices for its generic Intuniv.

107. Shire's agreement with Anchen, permitting Anchen to launch an authorized generic when Actavis launched its generic Intuniv caused Actavis to settle with Shire instead of launching after a favorable decision in the patent litigation to launch generic Intuniv, which would likely have occurred in May 2013. Even though Actavis knew that Shire's patents were weak and would likely not be upheld in the litigation, Actavis also knew that its profits during any 180-day generic exclusivity period would be vastly reduced if it had to compete with a Shire/Anchen authorized generic. Thus, Actavis chose to be the sole generic at a later time rather than enter the market earlier and have to compete with an authorized generic.

108. When Shire settled with Actavis, the agreement was collusive and intended to maintain a monopoly and allocate the market: it enabled Shire to continue to receive monopoly profits until December 1, 2014 and enabled Actavis to control the generic market for 180 days thereafter, with Shire sharing in the Actavis generic's profits.

109. Shire's sales of Intuniv were approximately $288 million in 2012, $335 million in 2013, and $327 million in 2014.

110. On June 2, 2015, at the end of Actavis's 180-day exclusivity period, Teva and Mylan launched their generic Intuniv. TWi launched a generic Intuniv on June 3, 2015, and Sandoz launched a generic Intuniv on June 4, 2015.

111. At this pre-discovery stage, the value of the reverse payment agreement to Shire and Actavis can be calculated using the known economics of the pharmaceutical industry.

112. On the Shire side, Shire entered into the reverse payment agreement in April of 2013, and the agreement delayed generic entry until December 1, 2014, a period of about 19 months. Intuniv sales for the period ending June 2014 were $335 million. With generic entry, Shire would have lost about 90% of its sales; without generic entry, it kept those sales. As a result, by reason of the reverse payment agreement, Shire realized about $477 million in *additional* branded sales over this period ($335 million × 0.9 × 19/12). By inducing Actavis to delay entry, Shire extended its monopoly period with Intuniv from at least May 1, 2013 through December 1, 2014, gaining almost one-half billion in additional sales.

113. On the Actavis side and under the anticompetitive conditions created by the agreement (i.e., not facing competition from an authorized generic), Actavis could expect to gain all of the generic sales during its 180-day exclusivity period. And without generic competition, Actavis would likely price its generic product at about 90% of the brand's price. As a result, during its 180-day exclusivity, Actavis would be estimated to realize about $136 million in generic sales revenue ($335 million × 0.5 × 0.9 × 0.9). Only about 5% of Actavis's revenue would go to covering the minimal costs of manufacturing and selling its product, meaning Actavis's net revenue during its six months of exclusivity would be approximately $129 million. After paying the 25% "royalty" to Shire, Actavis would earn approximately $97 million ($129 million × 0.75).

114. To understand the value of the no-AG promise from Actavis's perspective, this $97 million figure must be compared to what Actavis would expect to earn if it launched with its approved ANDA product on or about May 2013, but under the competitive conditions in which Shire (with Anchen) would have launched an authorized generic. Under those

competitive conditions, the authorized generic would take unit sales from Actavis and drive down the price Actavis could command for its product.

115. If Actavis launched under its ANDA in May 2013, generics would still take 90% of brand unit sales, but Actavis would split those sales about 50/50 with the Shire (with Anchen) AG product. Also, Actavis would have been able to charge only approximately half the brand price (because with two commodity products available, price drops steeply). So Actavis would gross only about $38 million during its 180-day period ($335 million × 0.5 × 0.9 × 0.5 × 0.5), and realize a profit of about $36 million ($38 million × 0.95).

116. Since Actavis would earn approximately $97 million under the anticompetitive conditions, but only about $36 million under competitive ones, the net payoff to Actavis for its agreement to delay entry may fairly be estimated at this time at about $61 million.

117. If Actavis had launched under its own ANDA in May 2013, it would have triggered the commencement of its 180-day exclusivity and ensured competition from an authorized generic. Thus, while Actavis could expect profits in the first six months of about $36 million, it risked dramatically reduced profits thereafter, from both loss of market share and further price erosion due to entry by other generics. Here, there were four generic competitors, in addition to Actavis, poised to enter the market – and with five generics dividing the generics' 90% share of the market at substantially reduced prices, Actavis could expect only modest profits after the expiration of its 180-day exclusivity.

118. Actavis could not have obtained the approximately $61 million payment or its equivalent even if Actavis had won the patent litigation case against Shire. Shire made this payment in exchange for Actavis's agreement to delay generic competition to Intuniv. Absent Actavis's agreement to abandon its patent challenge and delay entry into the market with an ANDA-approved generic Intuniv, Shire would not have agreed to make the payment.

119. The payment is large – it far exceeds the amount that Shire saved in litigation expenses by settling the patent case with Actavis. Well-established literature concludes that the median cost for an *entire* patent case with more than $25 million at stake is approximately $5.5 million.[2] Shire's future expected litigation costs at the time of the settlement with Actavis were minimal because, among other reasons, the patent case had already gone through trial and post-trial motion practice at the time of the settlement.

120. The value of the reverse payment agreement to Shire is far greater even than the value to Actavis, because the more than 18-month delay in generic entry protected Shire's monopoly pricing over that time.

121. Shire's reverse payment to Actavis guaranteed two distinct periods of noncompetition: (a) the period before generic competition, from at least May 1, 2013 through December 1, 2014, whereby Shire and Actavis allocated 100% of the market to Shire; and (b) the 180-day exclusivity period after Actavis's entry, whereby Shire and Actavis allocated 100% of generic sales to Actavis. So drug purchasers were overcharged twice: from at least May 2013 to December 2014, they were forced to pay overcharges of at least $430 million (paying $477 million to Shire for branded Intuniv that would have been available as a generic at 10% of the price, or $47.7 million). And during Actavis's exclusivity period, purchasers were forced to pay additional overcharges of over $60 million.

122. The defendants have no procompetitive explanation or justification for the reverse payment agreement.

123. Were it not for the agreement between Shire and Actavis, Actavis would likely have entered the market, at the latest, in May 2013 after prevailing in its patent litigation with

[2] *See King Drug. Co. of Florence, Inc. v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 417 (E.D. Pa. 2015); *see also* American Intellectual Property Law Association ("AIPLA"), *2011 Report of the Economic Survey – Median Cost of Patent Infringement Litigation.*

Shire, leading to immediate competition with a Shire/Anchen authorized generic, and full competition with other generics by November 2013. Instead, Actavis did not release its generic until December 1, 2014, Shire remained off the generic market for the following six months, and generic entry by other manufacturers did not occur until June 2015.

124. As a result of the actions by Shire and Actavis, which are unlawful and actionable under the federal antitrust laws, generic competition for Intuniv was delayed from at least May 2013 through June 2, 2015, requiring purchasers of the drug to pay substantially higher prices during that period.

## VI. EFFECTS OF THE SCHEME ON COMPETITION AND DAMAGES TO THE PLAINTIFF AND THE CLASS

125. Shire's sales of Intuniv were approximately $288 million in 2012, $335 million in 2013, and $327 million in 2014. These amounts total hundreds of millions of dollars more in sales than Shire would have achieved absent Shire's and Actavis's unlawful scheme to impair generic competition. Generic Intuniv products would have been priced at a fraction of the cost of brand Intuniv, and quickly captured most of the market for Intuniv.

126. Shire's and Actavis's overarching anticompetitive scheme impaired and delayed the sale of generic Intuniv in the United States and unlawfully enabled Shire to sell its Intuniv at artificially inflated prices. But for Shire's unlawful conduct, generic competitors would have been able to compete, unimpeded, with their own generic versions of Intuniv, at a much earlier date.

127. But for defendants' anticompetitive conduct, as alleged above, Shire/Anchen and Actavis would have both sold a generic Intuniv at risk beginning after a decision in the patent case in May 2013, and entry of multiple other generic manufacturers would have come six months later.

128. Were it not for the defendants' anticompetitive conduct, the Plaintiff and other members of the class would have: (1) purchased lower-priced generic Intuniv, instead of the higher-priced brand Intuniv, during the period when Actavis delayed its entry to the market; and (2) paid a lower price for generic Intuniv products during Actavis's 180-day exclusivity period.

129. As a consequence, the plaintiff and other direct purchasers have sustained substantial losses and damage to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

## VII. MARKET POWER AND MARKET DEFINITION

130. Prior to December 1, 2014, Shire had monopoly power in the market for Intuniv because it had the power to exclude competition and/or raise or maintain the price of Intuniv at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable. From December 1, 2014 through June 1, 2015, Shire and Actavis had substantial market power in the market for Intuniv and its generic equivalent, because they had the power to exclude competition and/or raise or maintain the price of brand (Shire) and generic (Actavis) Intuniv at supra-competitive levels without losing enough sales to make supra-competitive prices unprofitable.

131. Prior to June 1, 2015, a small but significant, non-transitory increase to the price of brand Intuniv would not have caused a significant loss of sales. From December 1, 2014 through June 1, 2015, a small but significant, non-transitory increase in the price of generic Intuniv would not have caused a significant loss of sales.

132. Brand Intuniv does not exhibit significant, positive cross-elasticity of demand with respect to price with any other guanfacine product or treatment for ADHD other than AB-rated generic versions of Intuniv.

133. Brand Intuniv is differentiated from all other guanfacine products, and all other ADHD treatments, other than the AB-rated generic versions of brand Intuniv.

134. Shire and Actavis needed to control only brand Intuniv and its AB-rated generic equivalents, and no other products, in order to maintain the price of Intuniv profitably at supra-competitive prices. Only the market entry of competing, AB-rated generic versions would render the Defendants unable to profitably maintain their prices for Intuniv without losing substantial sales.

135. Shire sold brand Intuniv and Actavis sold generic Intuniv, during the 180-day exclusion period, at prices well in excess of marginal costs and in excess of the competitive price, and, therefore, Shire and Actavis enjoyed high profit margins.

136. The Defendants have had, and exercised, the power to exclude generic competition to brand Intuniv.

137. The Defendants, at all material times, enjoyed high barriers to entry with respect to brand and generic Intuniv.

138. There is direct evidence of market power and anticompetitive effects available in this case sufficient to show the Defendants' ability to control the price of Intuniv and generic Intuniv, and to exclude relevant competitors, without the need to show the relevant antitrust markets. The direct evidence consists of, *inter alia*, the following facts: (a) generic Intuniv would have entered the market at a much earlier date, at a substantial discount to brand Intuniv, but for Defendants' anticompetitive conduct; (b) gross margins were at all times substantial; and (c) the Defendants never lowered the price of Intuniv in response to the pricing of other brand or generic drugs.

139. To the extent proof of monopoly power by defining a relevant product market is required, the Plaintiff alleges that the relevant antitrust market is the market for Intuniv and its AB-rated generic equivalents.

140. The United States, the District of Columbia, and the U.S. territories constitute the relevant geographic market.

141. Shire's market share in the relevant market was 100% until December 1, 2014, after which Shire and Actavis collectively had 100% market share in the relevant market until June 2, 2015, when Teva and Mylan launched generic Intuniv.

## VIII. MARKET EFFECTS

142. The Defendants willfully and unlawfully maintained their market power by engaging in an overarching scheme to exclude competition. The Defendants designed a scheme to delay competition on the products' merits, to further Shire's anticompetitive purpose of forestalling generic competition against Intuniv, in which Actavis cooperated in order to increase its own profits. The Defendants carried out the scheme with the anticompetitive effect of maintaining supra-competitive prices for the relevant product.

143. The Defendants implemented the scheme as described herein. These acts, in combination and individually, were undertaken to serve the Defendants' anticompetitive goals.

144. The Defendants' acts and practices had the purpose and effect of restraining competition unreasonably and injuring competition by protecting brand Intuniv, and later Actavis's generic Intuniv, from competition. These actions allowed the Defendants to maintain a monopoly and exclude competition in the market for Intuniv and its AB-rated generic equivalents, to the detriment of the Plaintiff and all other members of the direct purchaser class.

145. The Defendants' exclusionary conduct has delayed generic competition and unlawfully enabled Shire and Actavis to sell Intuniv without generic competition. Were it not for Defendants' illegal conduct, one or more generic versions of Intuniv would have entered the market sooner, and Actavis's generic would have faced competition during its 180-day exclusivity period from a Shire authorized generic.

146. By way of example, and not limitation, in the absence of the Defendants' conduct: (i) Actavis would have launched its generic Intuniv in May 2013 after the conclusion of its patent litigation with Shire; (ii) Shire/Anchen would have launched an authorized generic to compete with Actavis's generic; and (iii) six months after Actavis's launch, in November 2013, there would have been full competition from many other generic manufacturers, resulting in a much cheaper generic Intuniv. Instead, full competition did not actually occur until June 2015.

147. The Defendants' illegal acts and conspiracy to delay generic competition for Intuniv caused the Plaintiff and all members of the class to pay more than they would have paid for Intuniv absent this illegal conduct.

148. Typically, generic versions of brand drugs are priced significantly below the brand counterpart. As a result, upon generic entry, direct purchasers substitute generic versions of the drug for some or all of their brand purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and the brand drug, continues to lose even more market share to the generics. This price competition enables all direct purchasers of the drug to purchase generic versions at a substantially lower price, and/or purchase the brand drug at a reduced price. Consequently, brand drug manufacturers have a keen financial interest in delaying the onset of generic competition.

149. Generic companies holding first-to-file exclusivity likewise have a keen financial interest in delaying their entry into the market in exchange for maintaining generic exclusivity, and a share of the monopoly profits that their delay makes possible. Additionally, purchasers experience substantial cost inflation from these delays.

150. If generic competitors had not been unlawfully prevented from entering the market earlier and competing in the relevant markets, direct purchasers, such as the Plaintiff and members of the class, would have paid less for Intuniv by (a) paying lower prices on their remaining brand purchases of Intuniv, (b) substituting purchases of less-expensive generic Intuniv for their purchases of more-expensive brand Intuniv, and/or (c) purchasing generic Intuniv at lower prices sooner.

151. Thus, the Defendants' unlawful conduct deprived the Plaintiff and members of the class of the benefits from the competition that the antitrust laws are designed to ensure.

## IX. ANTITRUST IMPACT AND IMPACT ON INTERSTATE COMMERCE

152. During the relevant time period, the Defendants sold Intuniv across state lines.

153. During the relevant time period, the Plaintiff and members of the class purchased substantial amounts of Intuniv and/or generic Intuniv directly from the Defendants. As a result of the Defendants' illegal conduct the Plaintiff and the members of the class were compelled to pay, and did pay, artificially inflated prices for Intuniv and generic Intuniv.

154. During the relevant time period, the Defendants used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. All the Defendants engaged in illegal activities, as charged in herein, within the flow of, and substantially affecting, interstate commerce.

## X. CLASS ACTION ALLEGATIONS

155. The plaintiff brings this action on behalf of itself and all others similarly situated under Federal Rules of Civil Procedure 23(a) and 23(b)(3):

> All persons or entities in the United States and its territories, or subsets thereof, that purchased Intuniv and/or generic Intuniv in any form directly from Shire or Actavis, including any predecessor or successor of Shire or Actavis, at any time from at least May 1, 2013 until the effects of Defendants' conduct ceased (the "class").

156. Excluded from the class are Shire, Actavis, Teva, and any officers, directors, management, employees, subsidiaries, and affiliates of any of them.

157. Members of the direct purchaser class are so numerous and geographically dispersed that joinder of all members is impracticable. The Plaintiff believes that the class is numerous and widely dispersed throughout the United States. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The class is readily identifiable from information and records in the Defendants' possession.

158. The plaintiff's claims are typical of the claims of the members of the class. The Plaintiff and all members of the direct purchaser class were damaged by the same wrongful conduct of the Defendants – *i.e.*, as a result of the Defendants' conduct, they paid artificially inflated prices for Intuniv and any available AB-rated generic equivalents.

159. The plaintiff will fairly and adequately protect and represent the interests of the class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the other members of the class.

160. Counsel that represent the plaintiff are experienced in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigations involving pharmaceutical products.

161. Questions of law and fact common to the members of the class predominate over questions that may affect only individual class members, because the defendants have acted on grounds generally applicable to the entire class, thereby making overcharge damages with respect to the class as a whole appropriate. Such generally applicable conduct is inherent in the Defendants' wrongful conduct.

162. Questions of law and fact common to the class include:

a. Whether the Defendants unlawfully maintained monopoly power through all or part of their overall anticompetitive generic suppression scheme;

b. Whether there exist any legitimate procompetitive reasons for some or all of the Defendants' conduct;

c. To the extent such justifications exist, whether there were less restrictive means of achieving them;

d. Whether direct proof of the Defendants' monopoly power is available and, if so, whether it is sufficient to prove Defendants' monopoly power without the need to define the relevant market;

e. Whether the Defendants' scheme, in whole or in part, has substantially affected interstate commerce;

f. Whether the Defendants' scheme, in whole or in part, caused antitrust injury through overcharges to the business or property of the Plaintiff and the members of the class;

g. Whether Shire and Actavis conspired to delay generic competition for Intuniv;

h. Whether, pursuant to the reverse payment agreement, Shire's promise not to compete against Actavis's generic product constituted a payment;

i. Whether Shire's agreement with Actavis was necessary to yield some cognizable, non-pretextual procompetitive benefit;

j. Whether Shire's compensation to Actavis was large and unexplained;

k. Whether the reverse payment agreement created a bottleneck to further delay generic competition for Actavis;

l. Whether the reverse payment harmed competition;

m. Whether, prior to December 1, 2014, Shire possessed the ability to control prices and/or exclude competition for Intuniv;

n. Whether, from December 1, 2014 through June 1, 2015, Shire and Actavis possessed the ability to control prices and/or exclude competition for Intuniv;

o. Whether the Defendants' unlawful monopolistic conduct was a substantial contributing factor in causing some amount of delay of the entry of AB-rated generic Intuniv;

p. Determination of a reasonable estimate of the amount of delay the Defendants' unlawful monopolistic conduct caused, and;

q. The quantum of overcharges paid by the class in the aggregate.

163. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly-situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

164. The plaintiff knows of no special difficulty to be encountered in litigating this action that would preclude its maintenance as a class action.

## XI. CLAIMS FOR RELIEF

### COUNT ONE – CONSPIRACY IN RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. § 1)

(Against Shire and Teva)

165. The plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

166. On or about April 25, 2013, Shire and Actavis entered into a reverse payment agreement, a continuing illegal contract, combination, and restraint of trade under which Shire paid Actavis substantial consideration in exchange for Actavis's agreement to delay bringing its generic version of Intuniv to the market, the purpose and effect of which were to: (a) delay generic entry of Intuniv in order to lengthen the period in which Shire's brand Intuniv could monopolize the market and make supracompetitive profits; (b) keep Shire's authorized generic off the market during Actavis's 180-day generic exclusivity period, thereby allowing Actavis to monopolize the generic market for Intuniv during that period, and allowing Actavis to make supracompetitive profits, which were shared with Shire; and (c) raise and maintain the prices that Plaintiff would pay for Intuniv at supracompetitive levels until June 2015.

167. This reverse payment agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

168. Shire and Actavis are liable for this reverse payment agreement under a "rule of reason" standard under the antitrust laws.

169. There is and was no legitimate, non-pretextual, pro-competitive business justification for this reverse payment agreement that outweighs its harmful effect on direct

purchasers and competition. Even if there were some conceivable and cognizable justification, the payment was not necessary to achieve such a purpose.

170. As a direct and proximate result of Shire's and Actavis's anticompetitive conduct including the reverse payment, as alleged herein, the Plaintiff was harmed.

171. Teva acquired Actavis in August 2016, and succeeds to all of the Plaintiff's claims against Actavis.

**COUNT TWO – MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2)**
**(Against Shire)**

172. The Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

173. Until December 1, 2014, Shire possessed monopoly power in the relevant market and possessed the power to raise and maintain supracompetitive prices and/or exclude competitors from the relevant market.

174. Shire engaged in an exclusionary conduct scheme that involved paying Actavis to abandon its patent challenge and agree to delay its generic entry.

175. The goal, purpose, and/or effect of Shire's scheme was to maintain and extend its monopoly power with respect to Intuniv. Shire's illegal scheme to delay the introduction of generic Intuniv allowed it to continue charging supra-competitive prices for Intuniv without a substantial loss of sales.

176. If Shire had not arranged for other manufacturers of generic Intuniv, besides Actavis, to be prevented from entering the market until June 1, 2015, and had competed with Actavis's generic by selling an authorized generic, the Plaintiff and other members of the class would have purchased lower-priced generic Intuniv, and/or would have received lower prices

on some or all of their remaining brand purchases, at earlier periods of time and in far greater quantities.

177. As a result of Shire's illegal scheme, the Plaintiff and the class paid more than they would have paid for Intuniv, absent the illegal conduct. But for the illegal conduct, competitors would have begun marketing generic versions of Intuniv at a far earlier date, resulting in cost savings to the Plaintiff and other direct purchasers.

178. During the relevant period, the Plaintiff and the class purchased substantial amounts of Intuniv directly from Shire. As a result of Shire's illegal conduct, the Plaintiff and the members of the class were compelled to pay, and did pay, artificially inflated prices for Intuniv. The Plaintiff and all class members paid prices for Intuniv that were substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (a) class members were deprived of the opportunity to purchase lower-priced generic Intuniv instead of the more expensive brand Intuniv; and/or (b) the price of brand Intuniv and generic Intuniv were artificially inflated by Shire's illegal conduct.

179. The anticompetitive consequences of Shire's actions far outweigh any arguable procompetitive benefits. Shire acquired and extended a monopoly through unlawful means.

180. Shire's scheme was, in the aggregate, an act of monopolization undertaken with the specific intent to monopolize the market for Intuniv and generic Intuniv in the United States, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

## XII. DEMAND FOR JUDGMENT

WHEREFORE, the Plaintiff, on behalf of itself and the proposed class, respectfully demands that this Court:

a. Determine that this action may be maintained as a class action pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Federal Rule of Civil Procedure 23(c)(2),

be given to the class, and declare the Plaintiff as the representative of the class;

b. Enter joint and several judgments against the Defendants and in favor of the Plaintiff and the class;

c. Award the class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

d. Award the Plaintiff and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

e. Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

## XIII. JURY DEMAND

Pursuant to Fed. Civ. P. 38, the Plaintiff, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Dated: December 30, 2016

Respectfully submitted,

/s/ Thomas M. Sobol
Thomas M. Sobol (BBO #471770)
Kristen A. Johnston (BBO #632738)
Kristie A. LaSalle (BBO #692891)
Jessica R. MacAuley(BBO #685983)
HAGENS BERMAN SOBOL SHAPIRO LLP
55 Cambridge Parkway, Suite 301
Cambridge, Massachusetts 02142
Tel: 617-482-3700
Fax: 617-482-3003
tom@hbsslaw.com
davidn@hbsslaw.com
lauren@hbsslaw.com

John D. Radice (*PHV forthcoming*)
Daniel Rubenstein (*PHV forthcoming*)
RADICE LAW FIRM, P.C.
34 Sunset Blvd
Long Beach, NJ 08008
Tel: (646) 245-8502
Fax: (609) 385-0745
jradice@radicelawfirm.com

drubenstein@radicelawfirm.com

Joseph M. Vanek (*PHV forthcoming*)
David P. Germaine (*PHV forthcoming*)
Jeffrey R. Moran (*PHV forthcoming*)
John P. Bjork
VANEK, VICKERS & MASINI, P.C.
55 W. Monroe
Suite 3500
Chicago, IL 60603
Tel: (312) 224-1500
jvanek@vaneklaw.com
dgermaine@vaneklaw.com
jmoran@vaneklaw.com
jbjork@vaneklaw.com

Paul E. Slater (*PHV forthcoming*)
Matthew T. Slater (*PHV forthcoming*)
SPERLING & SLATER, P.C.
55 W. Monroe
Suite 3200
Chicago, IL 60603
Tel: (312) 641-3200
pes@sperling-law.com
mslater@sperling-law.com

*Attorneys for FWK Holdings, LLC. and the Proposed Class*